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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILSON, LARRY ROSS	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,898	MORIWAKI ET AL.	
	Examiner	Art Unit	
	LARRY R. WILSON	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application EP 1 048 311 A2 to Yosisuke Teraoka (Teraoka) in view of U.S.Patent 5,762,632 to Maxwell Edmund Whisson (Whisson).

In regards to claim 1, Teraoka teaches a medical needle device with a winged shield (Fig. 1, #1) comprising a winged shield (Fig. 1, #7 & 8), that has a substantially cylindrical shield tube (Fig. 1, #8) an a pair of wings (Fig. 1, #7), a hub that is inserted into an inner bore of the shield tube so as to be movable in an axial direction (col. 2, lines 22-27), a needle that is mounted to a front end of the hub (Fig. 1, #3), a rear end of the hub capable of being connected with an infusion tube (col. 7, lines 43-44) and a tip of the needle capable of being stored in the inner bore of the shield tube (col. 2, lines 26-27), the needle is inserted into and coupled with a bore of the hub at a front end thereof (Fig. 5, #11, 12 – shows the needle 11 inserted into the hub 12).

But Teraoka does not teach wherein at least a part of the hub is made of a material having flexibility, wherein that the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube and is latched to shield tube.

Whisson teaches wherein at least a part of the hub is made of a material having flexibility (col. 2, line 36), wherein the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube (Fig. 6 shows the extended position of the needle & col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable) and is latched to the shield tube (col. 4, lines 24-28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the flexible delivery tube and the flexible duct of Whisson as a hub and a shield tube, respectively, in the medical needle of Teraoka in order to allow for destructive bending or "kinking" of the delivery tube to render the infusion set incapable of further use (col. 4, lines 61-64) as explicitly taught by Whisson.

In regards to claims 2-7, Teraoka, as modified by Whisson teaches the medical needle device according to claim 1 (see rejection above), the shield tube is made of material having flexibility (col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable, the flexible tubular duct is a part of the shield tube); Teraoka further teaches wherein the shield tube (Fig. 1, #8) includes an extendable portion that is structured to be extendable and contractible (col. 5, lines 24-27), the needle can be moved in the axial direction of the shield tube by extending and contracting the extendable portion (col. 5, lines 27-29) and the shield tube and the hub are bendable at the extendable portion (implied the shield tube, as modified by Whisson, is flexible, the extendable portion of Teraoka is flexible otherwise it could not be extendable thus both are bendable); wherein the extendable portion has a plasticity-process accordion-like

structure (col. 5, lines 31-35); and when the shield tube and the hub in the inner bore of the shield tube are bent together, a minimum radius of curvature at a bent part can be 3 mm or smaller (implied in the flexible nature of the fluid delivery tube that holds the needle, as modified by Whisson, and the bendable accordion structure of the extendable member is capable of bending 3 mm or smaller, furthermore it would have been obvious to one of ordinary skill in the art to chose materials that would optimize the curve to allow the patient a greater range of motion such that conscious and unconscious movement does not remove the needle or damaging the vein. See MPEP 2144.05 II A - Optimization of ranges).

Response to Arguments

3. Applicant's arguments filed 10 July 2009 have been fully considered but they are not persuasive. The applicant's argument that there is no reasonable basis to modify the outer tube and inner connector tube in Teraoka with the flexible delivery tube and duct of Whisson is not persuasive because Whisson provides a reason for the flexible delivery tube such as to render the infusion set incapable of further use by kinking the delivery tube, which is in addition to the needle retention elements in the base 11. Additionally, if the flexible delivery tube and flexible delivery duct of Whisson would not provide adequate support when used in combination with the device of Teraoka it would not provide adequate support of the device according to Whisson either, because it would continue to function in the same way as it does in Whisson.

4. Applicant's argument that Teraoka only teaches the injection needle being supported by the infusion tube 4 and thus the Whisson delivery tube would not provide adequate support is not persuasive. Teraoka states "when the wing 7 and the protector 8 are separately formed and the

wing 7 is rotatably attached around the protector 8, a user conveniently can selected the direction of the injection needle when sticking the needle into a patient body" (col. 6, lines 51-55), this clearly implies that the protector 8 provides support if it is providing directional control while sticking the needle into the patient.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LARRY R WILSON/
Examiner, Art Unit 3767
/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767